

KP23473

**Attachment F
510(k) Summary**

Section 807.92(a)**(1) Submitter**

Implant Sciences Corp.
107 Audubon Road #5
Wakefield, MA 01880

Tel: 781.246.0700
Fax: 781.246.1167

Establishment Registration No.: 1226547

Contact Person: John J. Munro III
Vice President, Brachytherapy Products
e-mail: jmunro@implantsciences.com

(2) Device Name:

Classification Name: Radionuclide Brachytherapy Source (892.5730) (KXK)

Common or Usual Name: Brachytherapy Source Assembly

Proprietary Name: Seed Link

(3) Legally Marketed Predicate Device: Nycomed Amersham I-125 Rapid Strand, cleared under 510(k) number K940632 dated 2 September 1994, and

IBT, Inc. Interstrand 125, cleared under 510(k) number K011155 dated 12 July 2001, and

(4) Description of Seed Link:

Seed Link is a radionuclide brachytherapy source designed to incorporate a number of individual brachytherapy "seeds" into an integral assembly, and to maintain the specified spacing between the seeds during treatment. Seed Link incorporates the I-Plant Model 3500 interstitial brachytherapy seed, which has been previously cleared for marketing under 510(k) number K994317. Seed Link is an assembly of I-Plant 3500 interstitial brachytherapy seeds, sleeves and spacers designed to pass freely through an 18 Gauge thin-walled implant needle (which has an inside diameter of 0.041 inch (1.04 mm)). The length of the assembly is determined by the number of seeds to be joined and the spacing required between seeds. As a minimum, an assembly would contain two seeds and a spacing of 5.5 mm, resulting in an overall length of 14.5 mm. As many as six seeds may be incorporated into an assembly, and the spacing between seeds may be as large as 50 millimeters. The Seed Link shell and sleeve subassembly may also be supplied without attached spacers as individual "seeds".

KΦ23Φ73

(5) Intended Use

The intended use of Implant Sciences Corp. Seed Link is for the treatment of cancer by temporary or permanent interstitial, intracavitary, intraluminal, intraoperative or surface irradiation.

(6) Technological Characteristics:

Implant Sciences' Seed Link ¹²⁵Iodine Brachytherapy Seed Assembly is a radionuclide brachytherapy source designed to incorporate a number of individual brachytherapy "seeds" into an integral assembly, and to maintain the specified spacing between the seeds during treatment. Seed Link incorporates the I-Plant Model 3500 interstitial brachytherapy seed into a titanium sleeve, which is coupled to other seeds by means of a bioresorbable polymer spacer. Seed Link is provided sterile.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 07 2003

Mr. John J. Munro III
Vice President, Brachytherapy Products
Implant Sciences Corporation
107 Audubon Road, #5
WAKEFIELD MA 01880-1246

Re: K023073
Trade/Device Name: SeedLink™
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXX
Dated: January 10, 2003
Received: January 13, 2003

Dear Mr. Munro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number

Kd 23073

Device Name: Implant Sciences Seed Link

Indications for Use:

Implant Sciences Seed Link, containing Implant Sciences ^{125}I odine Brachytherapy Seeds with individual activities from 0.1 to 5.0 mCi are indicated for temporary or permanent interstitial, intracavitary, intraluminal or intraoperative implantation or surface application to treat selected localized tumors. They can be used either as primary treatment, such as for prostate cancer or for unresectable tumors, or as treatment for residual disease after excision of primary or recurrent tumors. Seed Link may be used concurrently with or following treatment with other interventions, such as external beam therapy, hyperthermia or chemotherapy. Tumors of the head, neck, lung, pancreas, prostate, breast and other accessible tumors are commonly treated.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

David A. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023073

(Optional Format 1-2-96)